UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/070,406 | 10/07/2002 | Ralf-Christian Scholthauer | DAIRY 71.001APC | 6927 |

20995 7590 01/05/2006

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

| EXAMINER | |
|---|---|
| PRATS, FRANCISCO CHANDLER | |
| **ART UNIT** | **PAPER NUMBER** |
| 1651 | |

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/070,406 | SCHOLTHAUER ET AL. | |
| | Examiner | Art Unit | |
| | Francisco C. Prats | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19,22-30 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-16 and 19* is/are allowed.

6)☒ Claim(s) *17,18,22-29 and 32-34* is/are rejected.

7)☒ Claim(s) *30, 35 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**DETAILED ACTION**

The amendment filed October 21, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-19, 22-30 and 32-36 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18, 22, 23, 27-29 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ju et al (J. Dairy Sci. 78:2119-2128 (1995)).

Ju discloses the hydrolysis of whey protein isolate (WPI) with Neutrase ®, at pH 7.0 (with a shift to 6.5-6.7 during hydrolysis) and 40° C, the reaction being stopped by dilution and pH change to 2.5 degree. See page 2120, left column, paragraph entitled "Hydrolysis of WP." The final degree of hydrolysis was 8.4 ± 1.2%. Thus, because Ju contacts the

claimed substrate with the claimed enzyme under the claimed conditions to result in the claimed degree of hydrolysis, a holding of anticipation of the cited claims over Ju is required.

Note specifically that, despite the amendment requiring an enzyme to substrate ratio of 0.01% to 3%, Ju is considered to anticipate those claims reciting specific peptides because the same starting material as recited in the claims was combined with the same enzyme as recited in the claims, and subjected to the same hydrolytic conditions to achieve the same degree of hydrolysis. Thus, while the rate of hydrolysis will be slower in the claimed reaction when compared to the prior art reaction, the peptide profile will necessarily be the same. Therefore the same result must inherently have occurred, and that inherent result includes the production of a hydrolysate comprising the specific peptides recited in applicant's claims.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant urges that the peptide profile of the hydrolysate of Ju is different than the peptide profile produced by the amended process claims because the reduction in enzyme amount in the claimed process results in a reduced hydrolysis of primary peptides, since the rate of hydrolysis of primary peptides to secondary peptides is proportional to the enzyme

concentration. However, it is respectfully pointed out that lowered enzyme amount will decrease the rate of hydrolysis of all peptides, including primary and secondary peptides. That is, the rate of hydrolysis of all peptides, not just primary peptides, is proportional to the amount of enzyme present. Thus, while the overall rate of the hydrolysis will be slower due to the lower relative amount of enzyme, the peptide profile will remain the same at any given degree of hydrolysis. While it is conceded that the process having more enzyme will proceed more quickly, and therefore have a different peptide profile at any given point in time after the reaction initiates, the peptide profile will necessarily be the same once any particular degree of hydrolysis is achieved.

Further still, with respect to the fact that the different temperatures used by Ju (40°C in Ju, versus 50°C in applicant's Example 1) and different substrate concentrations used by Ju (12% in Ju, versus 4% in applicant's Example 1) would necessarily result in a different product, note specifically that the values for these parameters are encompassed by the present language of claim 1. The only difference between the process claims and the process of Ju is that the reaction would proceed slower. Thus, in this regard applicant is technically arguing about a difference which is not present in the claims.

The language of claim 1 encompasses precisely the temperature and substrate concentrations alleged by applicant to result in conditions (e.g. weak gel formation and protein/protein interaction alleged to restrict enzyme to molecule access) which would deleteriously affect the hydrolysis process. Therefore, if Ju's process yields such effects on the hydrolysis, then applicant's process as presently claimed yields the same result.

Again, it is respectfully submitted that the product recited in the claims would necessarily result by performing the process disclosed by Ju, in view of the fact that the same substrate is contacted by the same enzyme, to result in a product having the same degree of hydrolysis. Absent direct evidence to the contrary, it is respectfully submitted that the anticipation rejection over the cited product claims must be maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 18, 22-29 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlothauer et al (WO 99/65326) in view of Ju et al (J. Dairy Sci. 78:2119-2128 (1995)).

Schlothauer describes the production of polypeptides from whey using neutral proteases including Neutrase (see, e.g., claims 6-8 on page 20), acid proteases (see Example 14 on pages 13 and 14), and alkaline proteases (see page 5, lines 15-16). Schlothauer describes the claimed variety of deactivation methods recited in claims 5-10 (see, e.g., pages 5-6), as well as the claimed immobilization techniques (page 5, lines 5-8). Schlothauer further discloses the preparation and use of the peptide MKG as recited in claims 15, 18, 21, 27 and 33 (see, e.g., page 4, lines 33-36).

Schlothauer differs from the claims under examination in that Schlothauer does not disclose the use of WPI as the starting material in the hydrolysis processes. However, Schlothauer generically discloses that the desired bioactive peptides can be made from a "whey protein containing substrate" (page 4, first line). Thus, the artisan of ordinary skill, recognizing from Ju that WPI is a whey protein containing substrate which can be hydrolyzed by the enzymes disclosed in Schlothauer, clearly would have been motivated to have used Ju's WPI in Schlothauer's process which uses a whey containing substrate. Thus, because WPI specifically fits the category of starting material required by Schlothauer, the artisan of ordinary skill would have been motivated to have used it in Schlothauer's process.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. With respect to claims directed to processes of making a hydrolysate from WPI, and the use of such a hydrolysate in treating hypertension, the obviousness rejection over these references has been withdrawn in view of the fact that the specification demonstrates the WPI hydrolysate made as claimed to be nearly twice as potent as hydrolysate made by essentially the same steps using a WPC substrate (e.g., specification at

page 17). However, remaining product claims 24-26 differ from the Ju reference only in that they recite a particle size limitation (claims 24 and 25) or clarity limitation (claim 26) which is not explicitly disclosed in that reference. However, Schlothauer clearly discloses the desirability of these properties. Moreover, on the current record, applicant has failed to demonstrate that particle size or clarity in any way results in the demonstrated improvements obtained by using WPI. Thus, it is respectfully submitted that the obviousness rejection over product claims 24-26, in addition to the obviousness rejection over product claims 17, 18, 22, 23, 27-29 and 32-34, is properly maintained, absent some demonstration of a difference between the prior art and the claims in this respect, or a demonstration of unexpected result coming from the use of a specific particle size or hydrolysate clarity.

Claims 1-16 and 19 are allowed. Claims 30, 35 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP